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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/827,100	04/05/2001	Chung Shih	T8418.NP	5014
20551	7590 11/20/2002			
	ORTH WESTERN		EXAM	INER
8180 SOUTF P.O. BOX 12	I 700 EAST, SUITE 200 19		DEWITTY, ROBERT M	
SANDY, UT	84070		ART UNIT PAPER NUMBER	
			1616	THE ENTROPER
•				
			DATE MAILED: 11/20/2002	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary Examiner	→ e ¹ \	· È	Application No.	Applicant(s)				
## Examiner Robert M DeWritty 1616 ## The MAILING DATE of this communication appears on the cover sheet with the correspondence address − Period for Reply ## A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. ## Extensions of these rays to analistic under the provisions of 37 CF3 1.138(s), in an event, however, may a reply be timely filed. ## If the period for reply specified above, the naminum stabulary period will apply and will expire SK (8) MXXPTRE for the nating date of this communication for reply specified above, the naminum stabulary period will apply and will expire SK (8) MXXPTRE from the nating date of this communication for the communication of the com	Office Action Summary		09/827.100	SHIH ET AL.				
Robert M DeWitty 16:16								
Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of the map by a emibble under the provides of 37 CPR 1.73(a), in no event, however, may a reply be timely filed Extensions of the map by a emibble under the provides of 37 CPR 1.73(a), in no event, however, may a reply be timely filed Extensions of the reply separation but one the provides of 37 CPR 1.73(a), a reply whiten the situation yre inflamman of thinly (20) days, as will be considered timely. If NO period for reply separation does, the maximum statutory period will apply and will expise x \$(8) ANOTH'S from the making date of this communication. If all provides the reply separation is the solid of the provided in the solid replaced of the communication. If the period for reply separation the provides and the solid replaced of the communication. If the period for reply separation is the solid replaced of the communication. If the period for reply separation is the solid replaced of the communication. If the period for reply separation is the solid replaced of the communication. If the period for reply separation is the solid replaced of the communication. If the period for replaced is the solid replaced of the communication. If the period for replaced is the solid replaced of the communication. If the period to replaced is the solid replaced in the solid replaced of the communication. If the period to replaced is the solid replaced in the solid replaced of the communication. If the period communication is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Queryle, 1935 C.D. 11, 453 O.G. 213. Ispansition of Claims Ispansition of the above claim (s) £15-39, 47 and 48 is/are withdrawn from consideration. I								
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of emergy be existed under the previous of 37 CPR 1.108(a). In no event, however, may a reply be timely filed Extensions of emergy be specified above is less than thirty (30) days, a reply when the statutory infrind many of the period for reply specified above is the statum to reply will, by attention of the reply specified above is the statum to reply will, by attention and part of the period for reply will, by attention of the reply will, by attention to reply will, by attention to the communication, well timely filed, may return a statum adulatment. Sea 37 CPR 1.704(b). Status 1) Responsive to communication(s) filled on 31 October 2002 22) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-56 is/are pending in the application. 4a) Of the above claim(s) 6, 15-39.47 and 48 is/are withdrawn from consideration. 5) Claim(s) 1-57-14.40-46 and 49-56 is/are rejected. 7) Claim(s) 1-57-14.40-46 and 49-56 is/are rejected. 7) Claim(s) 1-67-14.40-46 and 49-56 is/are rejected. 7) Claim(s) 1-67-14.40-46 and 49-56 is/are rejected or by the Examiner. Application Papers 9) The specification is objected to by the Examiner. Application Papers 1) The drawing(s) filed on 156/are: a) accepted or b) objected to by the Examiner. Application proved, corrected drawings are required in reply to this Office action. 12) The proposed drawing correction filed on 156/are: a) approved by the Examiner. 11 approved, corrected drawings are required in reply to this Office action. 12 Craim of the correction of the priority documents have been received. 2 Certified copies								
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Art Unit: 1616

DETAILED ACTION

Claims 1-56 are pending in the instant application. Acknowledgement is made of Applicant's election of invention, Group I, claims 1-14, 40-47, and 49-56 and the Election of Species.

Election/Restrictions

1. Applicant's election with traverse of Group I in Paper No. 7 is acknowledged. The traversal is on the ground(s) that if Group I were to issue and Group II were to issue, this would be problematic because the groups would contain the same independent claim. This is not found persuasive because the restriction was made based on the fact that claims 15-19 are dependent on claim 1. Thus, it is understood by the examiner that the protein in claim 1 would have different meanings for claims 15-19 (the protein being a plurality) and Group I (the protein not being drawn to a plurality).

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 2. Claims 1-5, 7-8, 10, 12, 14, 40-46, 49, 51, 53, 55-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Johnson et al. (U.S. Pat. No. 5,891,478).

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Johnson et al. is directed to a composition for sustained release of biologically active hGH (abstract). Stabilized hGH comprises active hGH complexed with a metal cation; the stabilized hGH is in particulate form (col. 2, lines 37-42). A preferred metal cation used to stabilize hGH is Zn⁺² (col. 2, lines 55-58). The molar ratio of metal cation component to hGH is 4:1 to about 100:1 (col. 2, lines 51-54). In forming the composition, stabilized hGH is dispersed in a polymer solution (col. 4, lines 63-67). A polymer suitable for the sustained release composition must be biocompatible (col. 3, lines 20-22). Suitable polymers may be copolymers. Further, the terminal functionalities of the polymer can be blocked (col. 3, lines 39-43). In one embodiment, a hGH sustained release composition contains from about 0.01% to about 50% of stabilized hGH particles (col. 4, lines 7-10).

3. Claims 1, 5, 7-9, 40, 46, 49, 50, 52-56 are rejected under 35 U.S.C. 102(b) as being anticipated by DePrince et al. (U.S. Pat. No. 4,765,980).

DePrince teaches methods for stabilization of porcine growth hormone (col. 2, lines 16-17). The growth hormone can be in the form of a metal complex Zn-pGH (col. 2, lines 58-61). The stabilized growth hormone can be administered via an implant device (col. 2, lines 30-32). The implantable delivery device can be made of materials that are biologically compatible with body fluids, tissues, and organs (col. 4, lines 26-40). Because DePrince teaches a Zn complex (limitation of instant claim 5), attached to a growth hormone (limitation instant claim 7) which can be used in an implant (limitation instant claim 9), as well as methods for preparing the implant device (limitation instant claim 40), the instant invention is anticipated.

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Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 7-13, 55, 56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 6, 12, 18-21, 24, and 25 of U.S. Patent No. 6,287,588. Although the conflicting claims are not identical, they are not patentably distinct from each other because the **588 patent it would have been within the skill on one in the art because **588 clearly teaches a biocompatible phase, microparticles, and an agent. It is the examiner's position that the biocompatible phase corresponds to the biocompatible matrix of the instant invention, the microparticles corresponds to the biocompatible particles of the instant invention, and the agent corresponds to the protein or peptide of the instant invention, such agent further being defined in claims 20 and 21.

Mentionable prior art not relied upon include Brodbeck et al. (U.S. Pat. No. 6.130,200) which teaches compositions for administering by implantation a beneficial

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agent, the compositions including a biocompatible polymer; and Cunningham et al. ("Dimerization of Human Growth Hormone by Zinc") which teaches that Zn²⁺ may modulate the release of growth hormone.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-398-

RMD

1235.

November 17, 2002

OSE G. DEES AMINER